K033421 (pg 1 of 2)

510K SUMMARY – Revised August 6, 2004

OCT 14 2004

Submitted By: ERBE USA, Inc.
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Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

510(k) Number: K033421

Date Prepared: August 6, 2004

Common Name: Bipolar Electrosurgical Open and Laparoscopic Instruments

Trade/Proprietary Name: ERBE BiClamp™ Open and Laparoscopic Instruments

Classification Name: Electrosurgical cutting and coagulation device and accessories (21CFR878.4400) and Gynecologic electrocautery and accessories (21 CFR Part 884.4120)

Product Code: GEI and HGI

Legally Marketed Predicate Device: Valleylab Inc. LigaSure™ Open and Laparoscopic Instruments, 510(k) Number: K981916

Device Description:

The ERBE BiClamp™ Open and Laparoscopic Instruments are used with an ERBE VIO Electrosurgical Generator (ESU) System having the Optional Bipolar Mode, BiClamp. High Frequency (HF) energy from the ESU is delivered through the jaws of the ERBE BiClamp™ Instruments to coagulate/desiccate tissue. The ERBE BiClamp™ Open Instruments are made of stainless steel with plastic insulation except at the jaw surfaces (which isolates the energy to only the jaw surfaces). The ERBE BiClamp™ Laparoscopic Instruments are made of metals and plastics with the electrical energy isolated to the jaws. They have various jaw types, which are standard in the industry. The ERBE BiClamp™ Open Instruments range in size from 200 mm (7.9 inches) to 270 mm (10.6 inches) in length with bent jaws that have a smooth surface. The ERBE BiClamp™ Laparoscopic Instruments have a 5 mm outside diameter (O.D.) and a 340 mm (13.4 inches) working length. The Instruments are provided non-sterile and are reusable (Note: The cleaning and sterilization processes have been validated and are provided in the Notes on Use to the customer.).

Intended Use:

The ERBE BiClamp™ Open and Laparoscopic Instruments are intended for use in general surgery, laparoscopic, gynecologic, urological, and thoracic procedures where fusion of vessels or tissues is desired. The devices can be used on vessels up to 7 mm and bundles as large as will fit in the jaws of the instrument. A vessel fusion is created by the application of bipolar electrosurgical RF energy (coagulation) to the vessels placed between the jaws of the instrument.

The ERBE BiClamp™ Open and Laparoscopic Instruments are designed for use with an ERBE VIO Electrosurgical Generator (ESU) System having an Optional Bipolar Mode/ BiClamp™ upgrade and the multi-function receptacle. Not recommended for use with other manufacturer's generators.

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The indications for use with Open Instruments include: general surgery, gynecologic, urological, and thoracic procedures where fusion of vessels and tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

The indications for use with Laparoscopic Instruments include: all laparoscopic procedures (including gynecologic, general, urological, and thoracic surgery) where fusion of vessels or tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies (gall bladder procedures), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

CAUTION: Vessel fusion can be affected by patient factors such as age, elasticity of vessels, thickness of vessel walls, etc.; therefore, the physician should review each vessel fusion for seal integrity. This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

Similarities and Differences of the Proposed Devices to the Predicate Devices Comparison/Substantial Equivalence):

Similarities

The ERBE BiClamp™ Open and Laparoscopic Instruments have similar physical and dimensional characteristics as the predicate devices. They have the same basic technological characteristics and the intended use is the same.

Differences

The ERBE BiClamp™ Open and Laparoscopic Instruments are different in that all of the product line components or parts are provided non-sterile and reusable; where as, the electrodes of the predicate's Open Instruments and Laparoscopic Instruments are sterile, single use. The ERBE BiClamp Open and Laparoscopic Instruments do not have closure mechanisms to hold the instrument closed (or clamped), where as, the predicate devices have closure mechanisms.

All the instrument designs have been verified or validated in design control by ERBE Elektromedizin GmbH.

Conclusion:

The ERBE BiClamp™ Open and Laparoscopic Instruments have the same intended use, principles of operation, and technological characteristics as the predicate devices that were previously cleared for market in a 510(k).

The ERBE BiClamp™ Open and Laparoscopic Instruments differ only in that all the instruments and their parts are reusable and they do not have a closure mechanism to hold the instruments closed.

In conclusion, there are no issues with the ERBE BiClamp™ Open and Laparoscopic Instruments that would raise additional safety or efficacy issues when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2004

ERBE USA, Inc.
c/o Ms. Julie Stephens
Regulatory Resources Group, Inc.
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K033421
Trade/Device Name: ERBE BiClamp™ Open and Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 23, 2004
Received: September 24, 2004

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use – REVISED August 6, 2004

510(k) Number (if known): K033421

Device Name: ERBE BiClamp™ Open and Laparoscopic Instruments

Indications For Use:

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The indications for use with Open Instruments include: general surgery, gynecologic, urological, and thoracic procedures where fusion of vessels and tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

The indications for use with Laparoscopic Instruments include: all laparoscopic procedures (including gynecologic, general, urological, and thoracic surgery) where fusion of vessels or tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies (gall bladder procedures), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033421